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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/600,025	08/29/2000	Philip J. Larkin		6639

7590 01/30/2002

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[REDACTED] EXAMINER

KRUSE, DAVID H

ART UNIT	PAPER NUMBER
1638	

DATE MAILED: 01/30/2002

8

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary	Application No.	Applicant(s)
	09/600,025	LARKIN ET AL.
	Examiner David H Kruse	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on ____.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-29 is/are pending in the application.

4a) Of the above claim(s) ____ is/are withdrawn from consideration.

5) Claim(s) ____ is/are allowed.

6) Claim(s) 1-29 is/are rejected.

7) Claim(s) ____ is/are objected to.

8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) The proposed drawing correction filed on ____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.

12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. ____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.

15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) Paper No(s). ____ .
2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) Notice of Informal Patent Application (PTO-152)
3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6 and 7. 6) Other: ____ .

DETAILED ACTION

Information Disclosure Statement

1. The Li 1997 reference in the IDS filed 13 February 2001 has been crossed out because it is duplicative of the same reference in the IDS filed 7 July 2000.

Drawings

2. The Draftsman has objected to the drawings as originally submitted, see the Form PTO 948, attached.

Specification

3. The disclosure is objected to because of the following informalities: The disclosure does not provide a description of each of the Figures on page 6 of the Specification.

Appropriate correction is required.

Claim Objections

4. Claims 4-23, 25-27 and 29 are objected to because of the following informalities:
At claims 4-23, the phrase "A method" should read -- The method --.
At claims 9 and 10, the phrase "in the pH" should just read -- in pH --.
At claims 25-27, the phrase "A transgenic plant" should read -- The transgenic plant --.

At claim 29, the phrase "Plant material" should read -- The plant material --.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-29 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

At claims 1-3 and 12-18 the phrase "exogenous genetic material" is indefinite because it is unclear what the metes and bounds of this limitation are. The breadth of said phrase may encompass chromosomes, chromosomal fragments, isolated nucleic acids comprising a coding region, whole genomes, etc. Clarification is required.

At claims 1-3, 7, 8, 28 and 28, the phrase "plant material" is indefinite because it is unclear what is encompassed by this limitation. It is suggested that the claims be amended to read -- a plant or plant explant -- to more clearly define the "plant material" used in the transformation method(s).

At claims 5 and 26, the phrase "the *Papaver* species" is indefinite because it lacks a proper antecedent basis. It is suggested that "the" be replaced with -- a --.

Claim 8 is rejected as indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of..." with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 2173.05(h). In addition the claim does not constitute a proper list of species because of the multiple use of the conjunctions "and" and "or".

Claim 11 is rejected as indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group consisting of..." with

the use of the conjunction "and" rather than "or" in listing the species (see lines 3 and 4). See MPEP 2173.05(h).

At claim 11, lines 4-5, the phrase "a modified ammonium and nitrate ion content in a predetermined ratio" is indefinite because it is unclear what the metes and bounds of the limitation are, in addition the phrase appears contradictory.

At claim 20, line 2, the phrase "is comprised in a DNA construct" is unclear, it is suggested that the phrase be amended to read -- comprises a DNA construct --.

Claim 27 is indefinite because the phrase "the species is" cannot further limit "*Eschscholtzia* species" but must limit "*Papaver* species". Insertion of -- *Papaver* -- before "species" would overcome the rejection.

Claim 28 is indefinite because it is unclear if Applicant is referring to the transformed plant material or the untransformed plant material. In addition, the phrase "Plant material when prepared by a method" is unclear, it is suggested that the phrase be amended to read -- The transformed plant material produced by the method --.

Claims 5, 16 and 29 are rejected as indefinite for being in improper Markush format. The Office recommends the use of the phrase "selected from the group *consisting of...*" with the use of the conjunction "and" rather than "or" in listing the species. See MPEP 2173.05(h).

7. The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 21-23 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel vectors (pTAB101 with 35S 5':*pat*:35S 3', pBSF16 and pPOP5). Since the vectors are essential to the claimed invention they must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the vectors are not so obtainable or available, a deposit of the vectors may satisfy the requirements of 35 USC § 112. The specification does not disclose a repeatable process to obtain the vectors and it is not apparent if the vectors are readily available to the public.

(a) If the deposit was made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

(b) If the deposit was not made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (i) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (ii) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (iii) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (iv) a test of the viability of the biological material at the time of deposit (see 37 CFR § 1.807); and,
- (v) the deposit will be replaced if it should ever become inviable.

9. Claims 1-5, 7-26, 28 and 29 are rejected under 35 U.S.C. § 112, first paragraph, because the specification, while being enabling for a method of producing a transgenic *Papaver somniferum* comprising a medium comprising a buffering agent, does not reasonably provide enablement for a method of producing any transgenic plant, or *Papaver* or *Eschscholtzia* species. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

Applicant claims a method of producing a transgenic plant comprising a medium comprising a buffering agent. In addition, Applicant claims said method wherein the plant is a *Papaver* or *Eschscholtzia* species.

Applicant teaches a method of transforming *Papaver somniferum* comprising a medium comprising a buffering agent (see Examples on pages 8-14).

Applicant does not teach a method of transforming or regenerating other *Papaver* species, nor does Applicant teach a method of transforming or regenerating other plants.

In re Wands, 858F.2d 731, 8 USPQ2d 1400 (Fed. Cir. 1988) lists eight considerations for determining whether or not undue experimentation would be necessary to practice an invention. These factors are: the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples of the invention, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicant has only provided guidance for a method of producing a transgenic plant within the scope of the plant species *Papaver somniferum*. The nature of the invention is such that the necessary transformation and culture conditions must be determined empirically for each plant species in order to produce optimal results. The art teaches that plant transformation remains an art because of the unique culture conditions required for each crop species (see Hanson *et al* 1999, Trends in Plant Science 4(6):226-230, specifically page 230, right column, first paragraph). Hence, it would have required undue trial and error experimentation by one of skill in the art at the time of Applicant's invention to determine the optimal buffer and pH requirements in addition to all of the other culture conditions required for each plant species or each poppy species in order to practice the invention as broadly claimed.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 1-3, 7-13, 24, 28 and 29 are rejected under 35 U.S.C. § 102(b) as being anticipated by De Block 1990 (Plant Physiology 93:1110-1116).

De Block discloses a method of producing a transgenic poplar plant comprising transforming a plant seedling stem explant with a heterologous gene and culturing callus and regenerating a transgenic plant comprising a medium comprising a buffering agent, specifically MES, using an *Agrobacterium tumefaciens* transformation method (see page 1111, right column). The medium disclosed by De Block was buffered to pH 5.5 (see Table 1 on page 1111). In addition, De Block discloses that the $\text{NO}_3^-/\text{NH}_4^+$ ratio in the culture medium is an important consideration when developing a transformation/regeneration protocol for a plant (see page 1110, right column, third paragraph). Hence, De Block has previously disclosed all of the claim limitations.

12. Claims 1-9, 11-13, 16, 17 and 24-29 are rejected under 35 U.S.C. § 102(b) as being anticipated by Yoshimatsu *et al* 1996 (pages 243-252 in Biotechnology in Agriculture and Forestry Vol. 38, Plant Protoplasts and Genetic Engineering VII (ed. by Y.P.S. Bajaj), Springer-Verlag, Berlin).

Yoshimatsu discloses a method of transforming *Papaver somniferum* callus explants derived from hypocotyls segment and regenerating a transgenic plant using a

half-strength MS medium having a modified ammonium and nitrate ion content (see pages 249-250). The Examiner's interpretation of the limitation "a buffering agent" in the instant claims has been applied broadly in view of Claim 11, thus "modified" ammonium and nitrate ion content of the half-strength MS medium of Yoshimatsu would inherently delay a rise in pH because of the lower concentration of ammonium ions in the medium. The transgenic poppy plant of Yoshimatsu produced an altered alkaloid proportions relative to the native alkaloid producing plant in terms of morphine and codeine content compared to that of a control poppy plant (see Table 2 on page 249). Hence, Yoshimatsu has previously disclosed all of the claim limitations.

13. The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(e), (f) or (g) prior art under 35 U.S.C. § 103(a).

15. Claims 24-29 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Yoshimatsu *et al* 1996 (pages 243-252 in Biotechnology in Agriculture and Forestry Vol. 38, Plant Protoplasts and Genetic Engineering VII (ed. by Y.P.S. Bajaj), Springer-Verlag, Berlin).

Yoshimatsu discloses a transgenic *Papaver somniferum* plant and explants produced by transforming a callus culture (see pages 249 and 250). The transgenic poppy plants of the reference differ from the claimed transgenic poppies only in their method of manufacture. However, the claimed process of utilizing a MES buffering agent would not confer a unique property to the resultant transgenic poppies. See *In re Thorpe*, 227 USPQ 964, 966 (Fed. Cir. 1985), which teaches that a product-by-process claim may be properly rejectable over prior art teaching the same product produced by a different process, if the process of making the product fails to distinguish the two products.

Claim Rejections - 35 USC § 103

16. Claims 14, 15 and 20 are rejected under 35 U.S.C. § 103(a) as being unpatentable over De Block 1990 (Plant Physiology 93:1110-1116) in view of Bidney (U.S. Patent 5,932,782).

The teachings of De Block are discussed above. De Block also teaches that poplar has been traditionally recalcitrant to transformation and regeneration (see page 1110, paragraph bridging the columns).

De Block does not teach a method of producing a transgenic plant wherein exogenous genetic material is introduced by a microparticle bombardment method. De Block also does not teach a pPZP-based vector.

Bidney teaches a method of producing a transgenic plant using *Agrobacterium* adhered to microprojectiles to transform a plant (see Claim 1). Bidney teaches that the method improves transformation in which plant cells are bombarded with microparticles, which carry an *Agrobacterium* species (see column 2, lines 27-30). Bidney suggests the use of the method for traditionally recalcitrant species (see paragraph bridging columns 3 and 4).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of Applicant's invention to modify the teachings of De Block using the method taught by Bidney. One of skill in the art would have had a reasonable expectation of success given the results taught by both Bidney and De Block in transforming plants, and given the suggestion by Bidney. Choice of publicly available binary vectors for plant transformation would have been the optimization of process parameters.

Conclusion

17. Claims 21-23 are deemed free of the prior art because the binary vectors of the instant claims appear to be unique constructs.
18. No claims are allowed.
19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (703) 306-4539. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (703) 306-3218. The fax telephone number for this Group is (703) 872-9306 Before Final or (703) 872-9307 After Final.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Kim Davis whose telephone number is (703) 305-3015.

DAVID T. FOX
PRIMARY EXAMINER
GROUP 180 1638

David H. Kruse, Ph.D.
25 January 2002

